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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,092	05/13/2005	Thomas C Kienzle III	14131US02	1923
23446 7590 11/03/2010 MCANDREWS HELD & MALLOY, LTD 500 WEST MADISON STREET SUITE 3400 CHICAGO, IL 60661				
EXAMINER				
JUNG, UNSU				
ART UNIT		PAPER NUMBER		
3768				
MAIL DATE		DELIVERY MODE		
11/03/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,092

Applicant(s)

KIENZLE, THOMAS C

Examiner

UNSU JUNG

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
4a) Of the above claim(s) 9-40 is/are withdrawn from consideration.
5) ☒ Claim(s) 41 is/are allowed.
6) ☒ Claim(s) 1-8 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 13 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date 6/25/2010
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. The Examiner for the current application has been changed from Salieu M. Abraham to Unsu Jung in Art Unit 3768. Any inquiry concerning this application should be directed to Unsu Jung, whose contact information is provided in the conclusion section of this Office Action.

Response to Amendment

2. Applicant's amendments in the reply filed on June 29, 2010 have been acknowledged and entered. The reply included amendments to claim 1.

Status of Claims

3. Claims 1-41 are pending, claims 9-40 have been withdrawn from consideration, and claims 1-8 and 41 are currently under consideration for patentability under 37 CFR 1.104.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The instant application is a national phase under 35 U.S.C. 371 of PCT International Application No. PCT/US03/36255, filed on November 13, 2003, which claims the benefit of U.S. Provisional Patent Application Serial No. 60/426,314, filed on November 14, 2002.

5. It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/Us03/36255, filed on November 13, 2003. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be

accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

6. The information disclosure statement filed on June 25, 2010 has been considered by the examiner.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following prior art rejection has been modified (**bolded passages**) due to amendment of independent claim 1 in the reply filed on June 29, 2010.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al. (U.S. Pat. No. 6,235,038 B1, May 22, 2001) (hereinafter "Hunter").

In Reference to Claim 1

Hunter teaches a system for tracking the position of an instrument relative to an area of interest (i.e. the surgical operating area; see abstract) comprised of a single or plurality of fixators (translational devices; see entire document, particularly Fig. 1) to include first (20), second (60, 80 or 100) or more (Abstract and column 5, lines 2-15) that can be secured to various points along an area of interest (Fig. 1 and column 5, lines 16-52), the fixators all being configured to carry interchangeable first and second localizing devices (optical or electromagnetic transmitters/receivers; column 5, lines 52-57) and whereby a third localizing device positioned proximate a third point along the area of interest (column 5, lines 2-15) such that *it is capable of communicating* with other localizing devices directly or indirectly such that its position relative to the other

localizing device(s) is known (column 5, lines 9-15).

With respect to the limitation of “said second localizing device at said first fixator is detached from said first fixator and attached to said instrument and said first localizing device at said second fixator is detached from said second fixator and attached to said first fixator”, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Hunter teaches that optical elements, which read on fixators of the instant claims, can be placed on variety of instruments and patient (column 5, lines 52-57). Since the fixators of Hunter can be detached and attached to different instruments/devices, the prior art structure of Hunter is capable of performing the intended use of “said second localizing device at said first fixator is detached from said first fixator and attached to said instrument and said first localizing device at said second fixator is detached from said second fixator and attached to said first fixator” as recited in claim 1 and the prior art structure of Hunter meets the claim.

In Reference to Claim 2

Hunter teaches the system of claim 1, wherein the first localizing device is an electromagnetic transmitter and the second and third localizing devices are electromagnetic receivers (column 6, lines 39-61)

In Reference to Claim 3

Hunter teaches the system of claim 1, wherein the first, second, and third localizing device are emitters for use in an optical tracking system (column 5, lines 53-58).

In Reference to Claim 4

Hunter teaches the system of claim 1, further comprising a computer system that monitors the communications between said first, second, and third localizing devices and calculates their relative positions (column 5, lines 25-26)

In Reference to Claim 5

Hunter teaches the system of claim 1, wherein additional localizing devices may be positioned about said area of interest (column 5, lines 7-9)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter (U.S. Pat. No. 6,235,038 B1, May 22, 2001) in view of Carlson (U.S. Patent No. 6,827,723 B2, filed Feb. 27, 2001).

In Reference to Claims 6-8

Hunter has been shown to teach all claim limitations to include image acquisition using imaging systems/modalities that commonly employ apparatus such as a C-arm (see rejection *supra* and column 1, lines 39-42), a fixator configured to carry an electromagnetic (EM) transmitter and receiver and fixator securement at different sites/locations as needed (e.g. a matter of design choice; Fig.1 and column 5, lines 16-58). However, Hunter does not specifically teach a C-arm having an imaging device and fixator securement by bone screws or connectable strap to a patient.

Carson discloses computer-based intra-operative systems and methods for obtaining anatomical images as well as registering, navigating and tracking target anatomical sites, surgical instruments and/or implants (see entire document particularly abstract). Carson's invention uses a C-arm with an imaging device (fig. 3) along with arthroscopic knee fixators (Figs. 2-3) to which EM transceivers can be attached (14) for

image registration, and surgical implement navigation and tracking (column 10, lines 35-67 and column 11, lines 1-12).

Therefore, it would be obvious to one of ordinary skill in the art to the employ trackable fixators as fiducials in the anatomical area being evaluated as a matter of design or study choice. It would be further obvious to one of ordinary skill that various fixator securement means could be employed in the surgical environment in order to ensure system accuracy for registration and tracking and that screw and connectable strap securements are commonly used in the art (Carson, column 8, lines 10-12 and art of record U.S. Patent No. 6,161,032 to Acker, see Fig. 1 and column 6, lines 53-56) as necessitated by the anatomical area under study and user choice. Lastly, it would be obvious to one of ordinary skill in the art to include C-arm apparatus and imaging device of Carson with the system of Hunter in order to facilitate intraoperative imaging as taught by Carson.

Allowable Subject Matter

12. Claim 41 is allowed.

13. The following is an examiner's statement of reasons for allowance: claim 41 is allowed because the prior art of record neither anticipates nor renders obvious the limitations of the claim with respect to setting and using localization device relative position thresholds based on a difference of any two of a plurality of device positions in order to make updated calculations of device positions and/or indicate a positional error.

Response to Arguments/Remarks

14. Rejection of claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Hunter

Applicant's arguments filed on June 29, 2010 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed herein.

In response to applicant's argument that Hunter does not teach or suggest that "said second localizing device at said first fixator is detached from said first fixator and attached to said instrument and said first localizing device at said second fixator is detached from said second fixator and attached to said first fixator", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Hunter teaches that optical elements, which read on fixators of the instant claims, can be placed on variety of instruments and patient (column 5, lines 52-57). Since the fixators of Hunter can be detached and attached to different instruments/devices, the prior art structure of Hunter is capable of performing the intended use of "said second localizing device at said first fixator is detached from said first fixator and attached to said instrument and said first localizing device at said second fixator is detached from said second fixator and attached to said first fixator" as recited in claim 1 and the prior art structure of Hunter meets the claim.

In view of the foregoing response to arguments, the rejection of claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Hunter has been maintained.

15. Rejection of claims 6-8 under 35 U.S.C. 103(a) as being unpatentable over Hunter in view of Carlson

Applicant's arguments filed on June 29, 2010 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed above.

In view of the foregoing response to arguments, the rejection of claims 6-8 under 35 U.S.C. 103(a) as being unpatentable over Hunter in view of Carlson has been maintained.

Conclusion

16. Claims 1-8 are rejected and claim 41 is allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/
Primary Examiner, Art Unit 3768